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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2607]

Agency Information Collection Activities: Proposed Collection; Comment Request; Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements relating to the manufacture and distribution of hearing aid devices.

DATES: Submit written comments on the collection of information by (*insert date 60 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burdens of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated collection techniques, when appropriate, and other forms of information technology.

Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control No. 0910–0171—Extension)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801.421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting,

fitting, and checking the performance of a hearing aid through distribution of a user instructional brochure. The user instructional brochure must also contain technical data about the device, instructions for its use, maintenance and care, a warning statement, a notice about the medical evaluation requirement, and a statement if the aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the user instructional brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the user instructional brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a user instructional brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the user instructional brochure to sellers for distribution to users and prospective users and provide a copy of the user instructional brochure to any health care professional, user, or prospective users who request a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by signing a written statement. Finally, the regulation requires that the dispenser retain for 3 years copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the user instructional brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired

because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.

The respondents to this collection of information are hearing aid manufacturers, distributors, dispensers, health care professionals, or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.420(c)	40	24	960	102	97,920
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,900	5	49,700	0.17	8,449
Total					586,369

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	62	1,600,000	0.25	400,000
Total					400,000

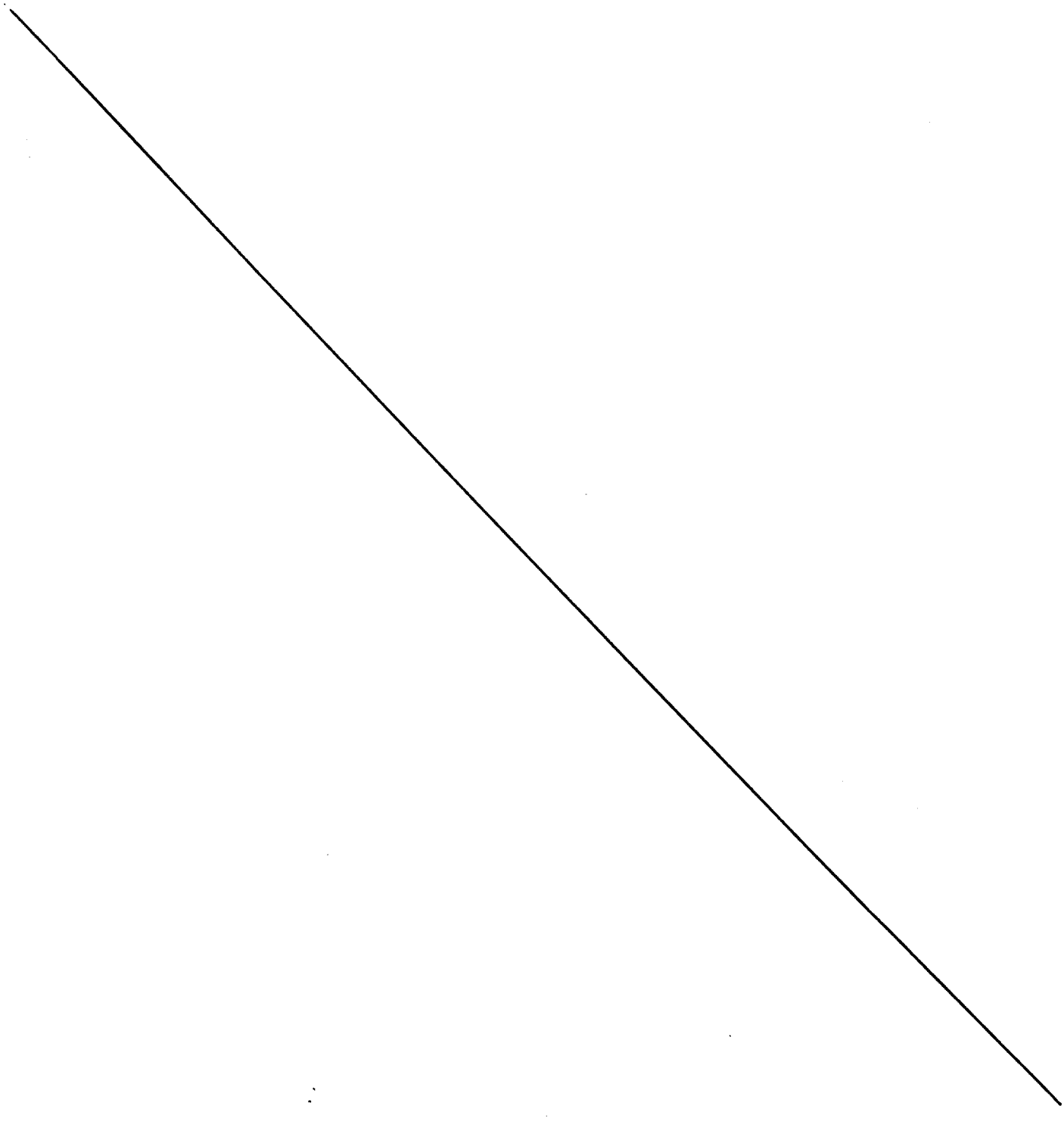
[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 801.420(c) estimate assumes that 40 hearing aid manufacturers or distributors each will distribute 5 different models of hearing aids. Thus, the 40 hearing aid manufacturers or distributors will provide 5 different user instructional brochures to sellers for distribution to prospective users and users. The completion of each user instructional brochure is estimated to require 102 staff hours.

Section 801.421(b) estimate assumes that 9,900 hearing aid dispensers will have 162 sales annually. For all such sales, the dispenser must provide the prospective user a copy of the user instructional brochure and the opportunity to read and review the contents with him or her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

Section 801.421(c) estimate assumes that 40 hearing aid manufacturers or distributors and 9,900 dispensers will provide copies of the user instructional brochure to any health care professional, user, or prospective user who requests a copy in writing. It is estimated that five

written requests for copies of the brochures will be received by each hearing aid manufacturer or distributor and dispenser annually. It is estimated that each request for a brochure will take .17 staff hours to complete. This effort consists of the hearing aid manufacturer or distributor or hearing aid dispenser locating the appropriate user instructional brochure for the specific model and mailing the brochure to the requester.



Section 801.421(d) recordkeeping estimate assumes that 9,900 hearing aid dispensers will each retain 162 records. Each record documents the dispensing of a hearing aid to a hearing aid user. The recordkeeping entry is estimated to require 0.25 staff hours.

Dated: AUG 18 1999

August 18, 1999

William Hubbard

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

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Michael W. Bell